

REMARKS

Claims 13-18 and 21-30 are pending in the application.

Claim Objection - Non-Elected Invention

Examiner has requested that the subject matter of claim 13 be incorporated into claim 28; this has been done with the instant amendment.

Rejection under 35 U.S.C. 103

Claim 28 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *US 6,086,851*.

Claim 28 has been amended to include the features of claim 13 and also a feature taken from the specification (page 2, lines 10-14) in regard to the spontaneous formation of the phospholipid gel when mixing the neutral and negatively charged phospholipids in water.

Examiner has argued that *US 6,086,851* discloses a method for moisturizing or calming skin / mucous membrane by administering a phospholipid gel that consists of a first and a second phospholipid, an inducer, and an antibiotic agent. Examiner argues that while the cited reference does not set forth the combination of neutral and negatively charged phospholipids, such a combination would be obvious in view of the brief list of phospholipids presented in the reference where neutral ones as well as negatively charged ones are mentioned.

Applicant respectfully submits that the method as now claimed in instant claim 28 requires the spontaneous formation of the phospholipid gel when mixing the neutral and the negatively charged phospholipids. No such method step is disclosed or suggested in the cited reference.

The cited reference discloses (see col. 7, lines 46-59) that the term "interdigitation-fusion gel (IF gel)" refers to a

"... product that results when an inducer is combined in sufficient

quantity with sized liposomes to fuse the liposomes such that lipids contained therein are interdigitated. ... The resulting sheets of lipid are fused gels for purposes of the present invention, and may include products of varying viscosity including liquids, gels and in certain cases, even very viscous products approaching the solid state."

The method described in the cited reference in connection with the topically used gels sets forth that (col. 10, lines 58ff):

"Also provided herein is an interdigitation-fusion gel comprising an interdigitated lipid and a bioactive agent. Preferably, the lipid is a symmetrical saturated phospholipid. The presence of an inducer in an effective amount will cause sized liposomes comprising such lipids to fuse, resulting in the formation of sheets of interdigitated lipid. While not being limited by way of theory, it is believed that sized liposomes fuse into lipid sheets (gels) at certain concentrations of inducer in order to relieve bilayer strain imposed by the liposomes' small radius of curvature (see, for example, FIG. 3). The resulting interdigitation-fusion gel that is produced may capture a high concentration of bioactive agent."

The gel according to the cited reference is produced from "sized liposomes" and, moreover, the method requires the presence of an inducer in an amount effective to induce lipid interdigitation from the sized liposomes. The sized liposomes according to col. 2, lines 25-28, typically have a "diameter of less than about 0.4 microns, preferably, less than about 0.05 microns and most preferably, less than about 0.025 microns".

Claim 1 of this reference also set forth that the interdigitation-fusion gel is prepared by the steps of:

"(a) preparing sized liposomes having an average diameter of less than about 0.40 microns and comprising a symmetrical saturated phospholipid;

(b) combining the sized liposomes with an amount of an inducer effective to induce fusion of the sized liposomes and interdigitation of the saturated phospholipid at a temperature and for a period of time effective to induce fusion of the sized liposomes and interdigitation of the saturated phospholipid, so as to form an interdigitation-fusion gel from the sized liposomes; and”.

Applicant would also like to point out that the reference teaches that a second lipid is added to the already formed gel as set forth in col. 3, lines 41 ff:

“In one embodiment of the invention, the method comprises adding a second lipid, for example, a non-interdigitating lipid, to the interdigitation-fusion gel prior to incubation. Preferably, the second lipid has a transition temperature in the gel less than the transition temperature of the first lipid in the gel.”

Col. 12, lines 29ff, also sets forth that additional materials such as lipids are added after the formation of the gel:

“In one embodiment of the invention, the method comprises adding additional material to the IF gel after its formation and prior to incubation to form IF liposomes. Aqueous-soluble compounds, such as bioactive agents, and lipid-soluble compounds, such as lipids and bioactive agents, can be added to the IF gel. Adding materials to IF gels after their formation is preferentially carried out for compounds which tend to interfere with interdigitation-fusion and which are not desirably part of the sized liposomes subject to interdigitation-fusion. Such compounds include non-interdigitating lipids, that is, lipids such as unsaturated lipids, mixed chain (saturated/unsaturated) lipids, such as SOPC and POPC, sterols and alpha-tocopherols which generally do not undergo interdigitation. Compounds added to IF gels after their formation can also include lipids which do

undergo interdigitation-fusion. The compound can be an additional lipid such as ...".

The cited reference therefore never discloses that first and second lipids (phospholipids) are mixed prior to gel formation; the second lipid is added after the gel is formed from the sized liposomes of the first (phospho)lipid.

The cited reference in particular does not teach that a neutral phospholipid and a negatively charged phospholipid spontaneously form a gel when mixed in water.

Claim 28 as amended is therefore not obvious in view of *US 6,086,851*.

Reconsideration and withdrawal of the rejection of the claim under 35 USC 103 are respectfully requested.

CONCLUSION

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on January 18, 2011,

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